IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
	)	
Manfred BOHN et al.	)	Group Art Unit: 1639
	)	
Application No.: 09/077,194	)	Examiner: Jon D. Epperson
	)	
Filed: May 26, 1998	)	Confirmation No. 5713
	)	
For: USE OF 1-HYDROXY-2-PYRIDONES FOR THE TREATMENT OF SEBORRHEIC DERMATITIS	)	

Mail Stop Appeal Brief—Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Pursuant to the Notice of Appeal filed on July 24, 2007, Appellants submit this Appeal Brief in accordance with 37 C.F.R. § 41.37, and enclose herewith the fee of $510.00 required under 37 C.F.R. § 41.20(b)(2). Appellants also file herewith a petition for a three month extension of time, extending the period for filing the Appeal Brief to December 24, 2007.

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I. Real Party in Interest

Sanofi-Aventis Deutschland GmbH is the assignee of record, as evidenced by the assignment recorded July 19, 2006, at Reel 017946, Frame 0877, and has licensed the invention under appeal to Medicis Pharmaceutical Corporation. As such, Sanofi-Aventis Deutschland GmbH and Medicis Pharmaceutical Corporation are both real parties in interest in this appeal.

II. Related Appeals and Interferences

With respect to appeals, interferences, or proceedings that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal, Appellants and Appellants' undersigned legal representative inform the Board of the Board's prior Decision in the present application, Appeal No. 2004-0309, mailed September 15, 2004, copy attached in the Related Proceedings Appendix at the end of this Brief. Appellants also filed an Appeal Brief on October 15, 2007, in related U.S. Application No. 10/606,229. The ongoing appeal in U.S. Application No. 10/606,229 has not yet been assigned an appeal number.

III. Status of Claims

Claims 38-42, 48, and 61-66 are pending and listed in the Claims Appendix of Part VIII.

The Examiner has rejected claims 38-42, 48, and 61-66 under one or more of 35 U.S.C. §§ 112, first and second paragraphs, 102(b), and 103(a) and under the judicially created doctrine of obviousness-type double patenting.

Claims 38-42, 48, and 61-66 are the subject of this appeal. As argued below, Appellants believe that the rejected claims are patentable.

IV. Status of Amendments

All amendments have been entered. No amendments have been made subsequent to the Reply After Final Under 37 C.F.R. § 1.113 filed June 4, 2007.

V. Summary of Claimed Subject Matter

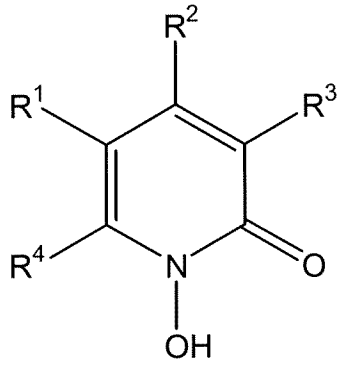
Seborrheic dermatitis ("SD") is a disorder of the scalp, which differs from dandruff by the presence of erythema (i.e., redness) as a sign of inflammation, by a greater degree of scaling with itching and burning, and by eczematous changes at other body sites besides the scalp. *See* specification at p. 1, ll. 3-7. On the scalp, SD can manifest in the form of patches, or affect the whole scalp and beyond, and can be accompanied by secondary infections. *Id.* at ll. 7-11. In contrast, dandruff is characterized by a clinically *noninflammatory* scaling of the scalp and occurs in almost all people. *Id.* at ll. 22-24 (emphasis added).

It is known that 1-hydroxy-2-pyridones exhibit activity against normal dandruff. *Id.* SD, however, was treated by other types of compounds, namely corticosteroids and antimycotics. *Id.* at ll. 26-28. The methods of the present invention use a single composition comprising as a sole active ingredient a 1-hydroxy-2-pyridone in the treatment of SD. The 1-hydroxy-2-pyridones described in the methods according to the invention as recited in the claims on appeal have several advantages over other treatments for SD. First, 1-hydroxy-2-pyridones exhibit both noninflammatory activity and antimycotic activity. *Id.* at ll. 30-37. Second, 1-hydroxy-2-pyridones have relatively broad anti-bacterial activity in that they are effective against Gram-positive and Gram-

negative aerobic and anaerobic bacteria, which can be important when, as often happens, secondary infections are involved in SD cases. *Id.* at p. 2, ll. 6-12. Finally, the solubility of 1-hydroxy-2-pyridones in water, alcohols, and aqueous-alcoholic solutions makes preparation of lotions and gels simpler. *Id.* at ll. 14-19.

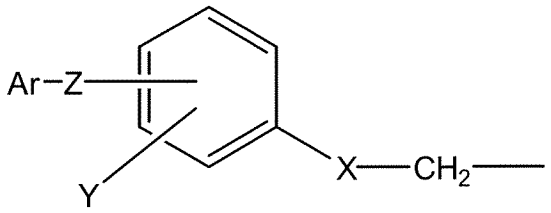
Independent claim 38 is directed to a method of treating seborrheic dermatitis in a human patient in need thereof comprising administering to the patient an amount effective for the treatment of seborrheic dermatitis of a single composition, wherein this composition comprises:

(A) a sole active component, which is a 1-hydroxy-2-pyridone of formula I or a pharmaceutically acceptable salt thereof:



(I)

where R^1, R^2, and R^3, which are identical or different, are H or alkyl having 1 to 4 carbon atoms, and R^4 is a saturated hydrocarbon radical having 6 to 9 carbon atoms or a radical of formula II:



(II)

where:

X is S or O;

Y is H, or 1 or 2 identical halogen atoms, or a mixture of 2 different halogen atoms;

Z is a single bond, or

a linking radical comprising

(1) O, or

(2) S, or

(3) $-CR_2-$, where R is H or (C_1-C_4)-alkyl, or

(4) from 2 to 10 carbon atoms linked in the form of a straight or branched chain, which optionally further comprises one or more of the following:

(i) a carbon-carbon double bond, and

(ii) O, S, or a mixture thereof, wherein if 2 or more O or S atoms or a mixture thereof are present, each O or S atom is separated by at least 2 carbon atoms; and,

in any of the foregoing linking radicals, any remaining free valences of the carbon atoms of said linking radical are saturated by H, (C_1-C_4)-alkyl, or a mixture thereof;

and

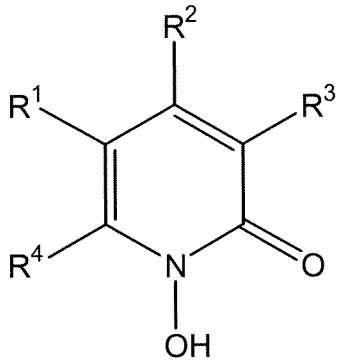
Ar is an aromatic ring system having one or two rings, the aromatic ring system being unsubstituted or substituted by one, two, or three radicals, which are identical or different, and are chosen from halogen, methoxy, (C_1-C_4)-alkyl, trifluoromethyl, and trifluoromethoxy; and

(B) at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants; and

wherein the composition has a pH ranging from about 4.5 to about 6.5. *See, e.g.,* specification at p. 1, lines 34-37; p. 2, ll. 6-12; p. 2, l. 25 to p. 3, l. 18; p. 5, l. 37 to p. 6, l. 2; p. 8, ll. 29-33; and Examples 1-3.

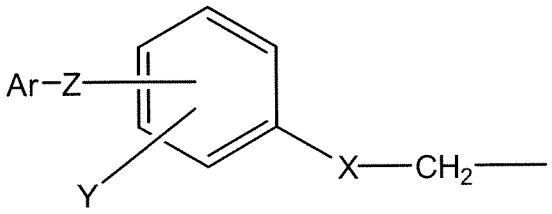
Independent claim 39 is directed to a method of treating seborrheic dermatitis in a human patient in need thereof comprising administering to the patient an amount effective for the treatment of seborrheic dermatitis of a single composition, wherein this composition comprises:

(A) a sole active component, which is a 1-hydroxy-2-pyridone of formula I or a pharmaceutically acceptable salt thereof:



(I)

where R^1, R^2, and R^3, which are identical or different, are H or alkyl having 1 to 4 carbon atoms, and R^4 is a saturated hydrocarbon radical having 6 to 9 carbon



(II)

atoms or a radical of formula II:

where:

X is S or O;

Y is H, or 1 or 2 identical halogen atoms, or a mixture of 2 different halogen atoms;

Z is a single bond, or

a linking radical comprising

(1) O, or

(2) S, or

(3) $-CR_2-$, where R is H or (C_1-C_4)-alkyl, or

(4) from 2 to 10 carbon atoms linked in the form of a straight or branched chain, which optionally further comprises one or more of the following:

(i) a carbon-carbon double bond, and

(ii) O, S, or a mixture thereof, wherein if 2 or more O or S atoms or a mixture thereof are present, each O or S atom is separated by at least 2 carbon atoms; and,

in any of the foregoing linking radicals, any remaining free valences of the carbon atoms of said linking radical are saturated by H, (C_1-C_4)-alkyl, or a mixture thereof;

and

Ar is an aromatic ring system having two rings, the aromatic ring system being unsubstituted or substituted by one, two, or three radicals, which are identical or different, and are chosen from halogen, methoxy, (C_1-C_4)-alkyl, trifluoromethyl, and trifluoromethoxy, and wherein Ar is a bicyclic system derived from biphenyl, diphenylalkane, or diphenyl ether; and

(B) at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants.

See, e.g., id. p. 1, lines 34-37; p. 2, ll. 6-12; p. 2, l. 25 to p. 3, l. 18; p. 3, ll. 31-34; p. 5, l. 37 to p. 6, l. 2; and Examples 1-3.

VI. Grounds of Rejection to be Reviewed

Claims 38, 40-42, 48, and 65 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey that the inventors had possession of the claimed invention at the time the application was filed. Final Office Action dated January 25, 2007 ("Final Office Action"), at 3.

Claims 38-42, 48, and 61-66 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for the terms "pharmaceutically acceptable salt" and "seborrheic dermatitis." *Id.*, at 5-7.

Claims 39 and 61-64 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by WO 96/02226 ("*Lagarde*"). *Id.*, at 9.

Claims 39 and 62-64 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by WO 88/00041 ("*Lange*") as evidenced by Green People (www.greenpeople.co.uk/Oganics_Features_SLS.htm) ("*Green People*") and Avre Skin Care (www.avro.co.za/misc/about_skincare/cosmetic_ingredients.html) ("*Avre*"). Final *Id.*, at 13.

Claims 38-42, 48, 53-58, and 61-66 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over *Lange* and 56 FR 63568 ("*FDA*") and WO 96/29045 ("*Dascalu*") in view of *Green People*, *Avre*, Dreumex (www.signus.com/dsoftsoap.htm) ("*Dreumex*"), U.S. Patent 6,514,490 ("*Odds*") and Brinkster (www.misterguch.brinkster.net/acidtutorial.html) ("*Brinkster*"). *Id.*, at 17-18.

Claims 38-42, 48, and 61-66 stand rejected under 35 U.S.C. § 102(b) or alternatively under 35 U.S.C. § 103(a) as allegedly anticipated or obvious over EP

0117135 A2 ("*Verdicchio*") in view of Janniger et al. (American Family Physician, July 1995, pp. 149-55) ("*Janniger*") and U.S. Patent 4,185,106 ("*Dittmar*"). *Id.*, at 30.

Claims 38-42, 48, and 61-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims 14-23 and 26-29 of U.S. Application No. 10/606,229. *Id.*, at 27.

VII. Arguments

A. Rejection Under 35 U.S.C. § 112, First Paragraph: The Specification Supports a Sole Active Component as Recited in Independent Claim 38

The Examiner rejects claims 38, 40-42, 48, and 65 under 35 U.S.C. § 112, first paragraph, for allegedly "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) . . . had possession of the claimed invention." Final Office Action at 3; Advisory Action of July 16, 2007 ("Advisory Action"), at 2. According to the Examiner, claim 38 recites "a sole active component consisting of at least one 1-hydroxy-2-pyridone of formula I . . . in free form or as a pharmaceutically acceptable salt." *Id.*, emphasis in original. The Examiner, however, states that he cannot find support for a "pharmaceutically acceptable salt" because the specification allegedly states that "when using the compounds in salt form, the adjustment of the pH . . . has to be carried out using organic acids." *Id.* Citing page 7 of the *Lange* reference (see discussion of § 102(b) rejections below), the Examiner further contends that "organic acids, including lactic acid, are known to possess anti microbial action." Final Office Action at 3; Advisory Action at 3. Based on these alleged facts, the Examiner concludes that Applicant "[has] not shown where support for . . . compounds that contain[s] '1-hydroxy-

2-pyridone of formula I salt + non active organic acids' can be found." *Id.* Appellants disagree.

1. The Legal Standard for Written Description

To satisfy the written description requirement under 35 U.S.C. § 112, first paragraph, a patent *specification* must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, Applicant was in possession of the invention as now claimed. See M.P.E.P. §2163.02. Here, Appellants submit that the Examiner improperly attempts to override the present specification's clear teaching with his own interpretation, citing to one isolated sentence out of *Lange* for "support." The focus of the written description requirement lies in what the specification at issue teaches, not what extrinsic evidence, such as a scientific article or another patent, purportedly says with respect to its own disclosure. As the M.P.E.P. instructs, the Examiner "must have a reasonable basis to challenge the adequacy of the written description. The Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an Applicant's disclosure a description of the invention defined by the claims." M.P.E.P. § 2163.04. Taking a single sentence out of a reference, and applying it in a way that contradicts the rest of the teachings of that reference, does not constitute a "reasonable basis" for challenging the adequacy of the specification's written description.

2. The Presence of an Organic Acid as a pH Adjuster Does Not Act as an Anti-seborrheic Agent

At the heart of this rejection is the Examiner's attempt to make the case that, in addition to the 1-hydroxy-2-pyridone recited in claim 38, any organic acid(s) used for pH

adjustment would also act as an active ingredient. Because claim 38 recites a "pharmaceutically acceptable salt," the Examiner assumes that organic acids must be present in the described composition based on the following passage at page 8, lines 30-33 of the present specification: "[w]hen using the compounds in salt form, the adjustment of the pH range mentioned has to be carried out using organic acids. . . . " The Examiner couples this passage with a single statement in *Lange* about using organic acids in phase II (described below) of their product, noting that "organic acids in the phase II composition, which acids *per se* possess an anti microbial action." *Lange*, at 7, last paragraph.

As stated above, the specification is the key to determining whether the written description requirement under 35 U.S.C. § 112, first paragraph, has been met. At page 8, lines 30-33, the present specification explains that "[w]hen using the compounds in salt form, the adjustment of the pH range mentioned has to be carried out using organic acids. . . . " This instruction says nothing about using organic acids as an active ingredient in the treatment of SD. Rather, this instruction simply informs the skilled artisan that, when a salt form of the 1-hydroxy-2-pyridone described in claim 38 is used in the invention, one should use an organic acid to adjust the pH. The skilled artisan would know that given the level of acid dilution that would occur when one uses an acid to adjust pH, any alleged antimicrobial activity it might have would not survive such a dilution. On this basis alone, one of ordinary skill in the art would recognize that Appellants were in possession of a composition in which the sole active component is a 1-hydroxy-2-pyridone as described in claim 38. And if one considers the *entirety* of

Lange, and not only the one sentence relied on by the Examiner, this reference supports the specification's teaching on this point, as Appellants will now explain.

Lange as a whole describes the use of a two-composition system to treat dandruff. The first composition, "phase I," is a detergent composition with a pH preferably in the neutral or weakly alkaline range. *Lange* at 6. The second composition, "phase II," "contains a solution of physiologically acceptable organic acid or mixture of these acids" and does not contain detergents. *Id.* at 3, second paragraph, and at 9, third paragraph. In discussing these two compositions, a detergent-containing shampoo and an acid-containing rinse, *Lange* clearly instructs that "soaps are not well suited for making lower pH products. . . Thus, the simultaneous action of the two previously mentioned compositions included in one shampoo is practically not feasible." *Id.* at 4, second full paragraph, emphasis added.

Therefore, *Lange*'s invention requires the use of two separate compositions, packed separately ". . . because both compositions may not be mixed without loss of effectivity . . . and because the synergistic effect of the components used in both liquids is only obtained if they are used one directly after the other!" *Id.* at 11, last paragraph, emphasis original. In other words, *Lange* teaches that when the acid is mixed with a detergent-containing solution, any alleged antimycotic effect is destroyed. Based on *Lange*'s teaching that the surfactant composition I must be kept separate from the acid composition II, one of ordinary skill in the art cannot conclude that an organic acid, when added to such a surfactant composition, would retain its alleged antimycotic activity, i.e., would still behave as an active ingredient. Thus, the entirety of *Lange* does not show that organic acids, *per se*, have antimicrobial activity. The Examiner contends

that *Lange* used organic acids to adjust the pH of the phase II composition. Advisory Action at 4. Even if this were true, it does not change the fact that the phase I composition and the phase II composition cannot be mixed without loss of antimycotic activity, according to *Lange*.

Appellants also wish to clarify the Examiner's misinterpretation of claim 38. Specifically, the Examiner states that claim 38 does not state that the described composition comprises a sole active ingredient against SD. Advisory Action at 4. Based upon this interpretation, the Examiner concludes that the claims preclude the use of all other active components whether they are useful in treating SD or not. *Id.* Appellants disagree with this interpretation of the claims. The Examiner's interpretation of claim 38 improperly considers this claim in a vacuum, rather than in light of specification's teachings on the treatment of SD. Moreover, claim 38 itself indicates that the "active component" is active against SD. Specifically, claim 38 recites "[a] method of treating seborrheic dermatitis in a human patient in need thereof comprising administering to the patient an amount effective for the treatment of seborrheic dermatitis of a single composition, wherein this composition comprises: . . . a sole active component . . . . " The preamble of claim 38 clearly connects the treatment of SD with the composition administered to the patient. The sole "active" ingredient in this composition to treat SD is an ingredient that is active against SD.

In sum, when reading the specification and the entirety of *Lange*, one of ordinary skill in the art would recognize that Appellants were in possession of a method of treating SD that uses a single composition comprising a sole active component, which is a 1-hydroxy-2-pyridone as described in independent claim 38. Because claims 38 and

its dependent claims 40-42, 48, and 65 are supported by the specification, the Board should reverse this rejection.

B. Rejections Under 35 U.S.C. § 112, Second Paragraph: Claims 38-42, 48, and 61-66 Are Definite

1. The Term "Pharmaceutically Acceptable Salt" Is Clear

Claims 38-42, 48, and 61-66 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite for reciting the phrase "pharmaceutically acceptable salt." According to the Examiner, the "pharmaceutically acceptable salt" embodiment "requires two active ingredients, (1) the salt of a compound of formula I and (2) the organic acid that is used to adjust the pH." Final Office Action at 6; Advisory Action at 5-6. In light of this interpretation, it is not clear to the Examiner "how the composition comprises a 'sole' active ingredient[s] when more than one active ingredient[s are] is being claimed." *Id.*

This indefiniteness rejection is effectively an extension of the Examiner's written description rejection above. Because claim 38 and 39 recite a "pharmaceutically acceptable salt," the Examiner concludes that the composition must have organic acid in it. Appellants contend that if the composition has organic acids in it, the acid is there merely to adjust the pH, as taught by the specification. Using his incorrect interpretation of *Lange*, the Examiner appears to reason that if an organic acid must be present due to the use of a salt form, then there must be more than one active ingredient according to *Lange*. Thus, in the Examiner's view, it is confusing how claim 38 and 39 can recite a sole active ingredient and a pharmaceutically acceptable salt at the same time.

Independent claim 38 does not require two active ingredients as the Examiner suggests. As Appellants explained above in Section (VII)(A)(2), *Lange* shows that an organic acid loses its antimycotic activity when mixed with a detergent. Thus, the organic acid, even if it were present in the composition of claims 38 and 39, would not be an active ingredient against SD. This is consistent with claim 38 and 39, which describe describes a composition in which a 1-hydroxy-2-pyridone is the sole active ingredient. Neither the specification nor *Lange* teach that an organic acid, when used adjust the pH of a detergent-containing composition, has an antimicrobial effect. Thus, the phrase "pharmaceutically acceptable salt" is not indefinite and the Examiner's rejection should be reversed.

2. The Term "Seborrheic Dermatitis" Is Clear and Has Been Used Consistently Throughout the Prosecution History

The Examiner also rejects claims 38-42, 48, 53, 55-59, and 61-67 as allegedly indefinite because the term "seborrheic dermatitis" is allegedly unclear in light of the prosecution history. According to the Examiner, *Dascalu* teaches the treatment of the "same exact symptoms as defined in Applicant's specification" and "that their treatment inhibits the exact yeast, Pityrosporum." Final Office Action at 7; Advisory Action at 7. Thus, the Examiner concludes, "it is not clear what symptoms, underlying causative agents and/or other physiochemical factors Applicants are relying on to make this distinction." *Id.*

When interpreting the meaning of a term in a claim, the Examiner should turn to the specification. Like the written description rejection discussed above, this indefiniteness rejection is another example of the Examiner's attempt to imprint his own

thinking over the teaching of the specification. Indeed, Appellants note that during the first appeal of this application, the Board turned immediately to the specification for guidance on the meaning of the term "seborrheic dermatitis." See Board's decision in Appeal No. 2004-0309, dated September 15, 2004, at 5. Thus, the Board has in the past acknowledged that the specification teaches a difference between SD and dandruff. *Id.* To assist the Examiner's understanding of this term, Appellants submitted a series of declarations that further describe the condition of SD.

As discussed above and on the record, the specification explains that SD is a condition of the scalp that differs from simple dandruff in that it is characterized by "erythema[, a] greater degree of scaling with occasional itching and burning, and by the occurrence of eczematous changes in other body sites." Specification, at 1, lines 3-11. Over the course of prosecution of this application, Appellants have submitted a series of declarations designed to further describe SD. The declaration of Dr. R. Todd Plott, dated July 17, 2006, was submitted in an Information Disclosure Statement in the present case on September 22, 2006. Dr. Plott, who is a board certified dermatologist and one of ordinary skill in the art, explains in his declaration that "dermatologists know that seborrheic dermatitis is an inflammatory disorder associated with the hyperproliferation of keratinocytes, while dandruff is a 'noninflammatory' scaling of the scalp. While both disorders can include flaking skin among their symptoms, they are known by dermatologists to be different disorders." Plott Declaration at 2. The Examiner noted in the Advisory Action that "it is interesting that Applicants' specification never mentions this important 'hallmark' (i.e., if 'hyperproliferation of keratinocytes' is the 'hall mark' that distinguishes seborrheic dermatitis from dandruff then why doesn't

the specification even mention it.") Advisory Action at 8-9. Appellants respectfully remind the Examiner that the inventor may describe the invention in any way he sees fit. Moreover, the specification was written with the knowledge of one of ordinary skill in the art in mind, i.e., the knowledge that a dermatologist would know. The declarations that Appellants submitted were for the Examiner's benefit, to educate him on that knowledge. Appellants discuss these declarations and show that their combination with the specification renders a consistent image of what SD is.

Likewise, Dr. James Leyden, who is a practicing dermatologist and one of ordinary skill in the art, instructs in his declaration dated January 4, 2006, submitted in an Information Disclosure Statement on September 22, 2006, that SD is a "disorder characterized by the hyperproliferation of keratinocytes in the skin. It is characterized by erythema (redness of the skin), scaling and yellow crusted patches. . . . Essentially, in seborrheic dermatitis, the epidermal keratinocytes multiply too quickly, causing scaling and other symptoms." Leyden declaration at 2.

Appellants also submitted a declaration by Dr. Mitchell S. Wortzman on June 9, 2003, during the first appeal of the present case. Appellants note that, during this first appeal, the Board entered this declaration into the record. Dr. Wortzman has a Ph.D. in cellular and molecular biology and has been involved in research and development for numerous dermatological products. Dr. Wortzman's declaration, dated June 6, 2003, explains that "dandruff is a 'noninflammatory' scaling of the scalp, while 'seborrheic dermatitis is an inflammatory erythematous, and scaling eruption that occurs in seborrheic areas . . . such as the scalp, face, and trunk.'" Wortzman declaration at 2. The Wortzman declaration further teaches that "even the scales of dandruff look

different from the scale from seborrheic dermatitis; dandruff has thin, white or gray flakes, while seborrheic dermatitis has oily, yellowish scales with inflammation." *Id.*

Each of the above descriptions contributes to a single, consistent description and definition of SD. In contrast, *Dascalu* does not describe the hyperproliferation of keratinocytes or the presence of "crusted patches" on the skin. Also, while *Dascalu* appears to generally describe scaling of the skin, *Dascalu* does not mention the "hyperproliferation of keratinocytes" that is the hallmark of SD (as noted by Dr. Leyden), nor does *Dascalu* teach "oily, yellowish scales," which result from this condition. The term "seborrheic dermatitis" is not indefinite, but rather is clearly defined in the specification and by the intrinsic evidence of record. Appellants accordingly request that the Board reverse this rejection.

C. Rejections Under 35 U.S.C. § 102(b)

1. Claims 39 and 61-64 Are Novel in Light of *Lagarde*

a) The Legal Standard for Anticipation

A claim is anticipated under 35 U.S.C. § 102(b) only if each and every element as set forth in the claim is found in a single reference. *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987) and M.P.E.P. § 2131. Furthermore, the identical invention must be set forth in as complete detail as it appears in the claim. See *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989) and M.P.E.P. § 2131. *Lagarde* cannot be said to anticipate the present invention because it does not disclose each and every element of the present claim, even when one takes the Examiner's supporting references into account.

b) The Examiner's Rejection

The Examiner rejects claims 39 and 61-64 under 35 U.S.C. § 102(b) as anticipated by *Lagarde* in view of two online sources, Wikipedia and *Green People*. The Examiner contends that *Lagarde* teaches a method for treating seborrheic dermatitits in a human patient in need thereof using a "combination product comprising an anti-fungal agent selected from the 1-hydroxy-2-pyridones such as ciclpirox [sic] or octopirox and, secondly, crotamiton as an antifungal agent activity enhancer." Final Office Action at 10; Advisory Action at 11. *Lagarde* also allegedly teaches, according to the Examiner, "at least one 1-hydroxyl-2-pyridone of formula I as the sole active component . . . . " and "the use of a surfactant . . . (. . . Cocamide DEA, Cocamide MEA, Cocamidopropyl betaine are disclosed)." Final Office Action at 10-11; Advisory Action at 11-12. Acknowledging that *Lagarde* does not state that Cocamide DEA, Cocamide MEA and Cocamidopropyl betaine are surfactants, the Examiner relies on an entry from Wikipedia to suggest that "these would be inherent properties of these molecules." Final Office Action at 11; Advisory Action at 12. The Examiner also points to *Green People* to allegedly show that sodium lauryl sulfate is an "anion surfactant" that is included in a variety of commonly used products including shampoo. *Id.* Regarding claim 61, *Lagarde* allegedly discloses the "cyclohexyl R4 group." *Id.* Regarding claim 64, *Lagarde* allegedly discloses "at least one 'additional' surfactant such as cocamidopropyl betaine + Cocamide MEA." *Id.* Appellants respectfully disagree with the rejection.

c) *Lagarde* Does Not Teach a Single Composition with a Sole Active Ingredient

The composition described in independent claim 39 contains "a sole" active ingredient, 1-hydroxy-2-pyridone. As the Examiner has acknowledged, *Lagarde* teaches a combination product that contains two active ingredients, 1-hydroxy-2-pyridone and crotamiton as an antifungal agent. And, as Appellants have argued on the record, *Lagarde* requires that his composition be a combination product that benefits from the "synergic association of products [the 1-hydroxy-2-pyridone and crotamiton]." *Lagarde* translation at 6. Indeed, *Lagarde* does not teach or even remotely suggest non-combination products, i.e., a "single" composition comprising a "sole" active component, or the use of 1-hydroxy-2-pyridones as a sole active component. Instead, *Lagarde* is entirely focused on the synergism resulting from the combination of his two active ingredients, i.e., the treatment of "skin fungal infections" with a composition comprising two separate compounds - 1-hydroxy-2-pyridone and crotamiton. *Id.* In contrast, the method of present claim 39 describes administering to the patient a single composition with a sole active component. The secondary references cited do not remedy the shortcomings of *Lagarde* in this regard.

Because *Lagarde* describes a "combination product" with more than one active ingredient and does not teach each and every element of independent claim 39 as required for a proper anticipation rejection, this reference does not and cannot anticipate claim 39 and its dependent claims 61-64. This rejection is simply not supported by *Lagarde* and therefore should be reversed by the Board.

2. Claims 39 and 62-64 Are Novel in Light of *Lange*

a) The Examiner's Rejection

The Examiner rejects claims 39 and 62-64 under 35 U.S.C. § 102(b) as allegedly anticipated by *Lange* "as evidenced by" *Green People* and *Avre*. Final Office Action at 13; Advisory Action at 13-14. The Examiner describes *Lange* as disclosing "a two phase cleansing, conditioning and medicinal treatment shampoo and methods of use. . . for treating seborrheic dermatitis." Final Office Action at 13; Advisory Action at 14, emphasis in original. *Lange* also allegedly teaches that the phase I composition "may contain anti-mycotics in the medicinal as well as the anti-dandruff variant" and that "one may use a water soluble anti-mycotic such as piroctone olamine." Final Office Action at 14; Advisory Action at 14. *Lange* also allegedly teaches sodium lauryl sulfate, which the Examiner contends is inherently an anionic surfactant "as exemplified by Green People" and "at least one 'additional' surfactant such as lauramide DEA," which the Examiner also contends is inherently a surfactant "as exemplified by Avre Skin Care." Appellants respectfully disagree with the rejection.

b) *Lange* Does Not Teach a Single Composition with a Sole Active Ingredient

Lange first appeared in the prosecution history of the present application in an Office Action mailed on October 24, 2001 at page 3. This reference has been cited as U.S. Patent 5,132,107 and currently, as WO 88/00041. Both U.S. Patent 5,132,107 and WO 88/00041 are in the same patent family and thus the arguments that Appellants made against U.S. Patent 5,132,107 in the prosecution history also apply to the WO 88/00041 publication. Despite the fact that the Board vacated a rejection that used

Lange as the central reference and noted, in its previous opinion in this case, that *Lange* was not the closest prior art, the Examiner continues to use *Lange* as a basis for anticipation. See Appeal Brief filed on December 16, 2002, at 6 and BPAI Decision mailed September 15, 2004 in Appeal No. 2004-0309, at 2 and 14.

As Appellants have consistently argued on the record and as discussed above in Section VII.A.2 of this brief, *Lange* teaches a product made of two separate compositions or phases. *Lange*'s first composition, phase I, has a neutral or weakly alkaline pH of 7.5-8.5 and contains detergents. *Lange*'s second composition, phase II, has an acidic pH and is applied separately, after the first composition was applied and rinsed out. Most importantly, *Lange* clearly teaches that combining phase I and phase II into a single composition is "not feasible." *Lange* at 4. Instead, *Lange* teaches that the two phases should not be packed together because "both compositions may not be mixed without loss of effectivity." *Lange* at 11. Clearly, *Lange* does not teach a single composition as recited in rejected claim 39. On this basis alone, *Lange* does not anticipate claims 39 and 62-64.

The Examiner, however, takes issue with Appellants' position on *Lange.* In the Advisory Action, the Examiner argues that present specification requires "multiple application[s] of the composition" to be applied over a period of time (e.g., a week), and concludes that "the claimed method of treating seborrheic dermatitis comprising the use of a single composition must not be construed to preclude the application of more than one composition later in time. Furthermore, Applicants[‘] use of 'comprising' open-ended terminology . . . would not preclude the use of 'additional' ingredients to those 'later' compositions." Advisory Action at 16-17. However, the issue is not whether the

same single composition is applied multiple times over a period of time for treatment, but instead whether, ***each time*** the treatment is administered, multiple compositions have to be applied at a single sitting. *See, Lange*, abstract, discussing the application of shampoo in two steps (referred to as phases), one following the other, to allow "sequential application of noncompatible substances." The present claims require application of one composition for treatment, not two or more. Accordingly, the rejection over *Lange* should be withdrawn for this reason alone.

Finally, even if one were to try and make a single composition from the two separate phases taught in *Lange*, the skilled artisan would have to pick and choose specific elements from *Lange* to arrive at the claimed single composition. *See* Amendment filed on April 24, 2002, at 21. Such picking and choosing, without guidance in the reference as to which elements should be combined, is not a proper foundation for anticipation. *Id.*, citing M.P.E.P. § 2131. If anything, *Lange* expressly counsels against making the combination described in the rejected claims. If the Examiner were to interpret *Lange* as teaching a single composition, that interpretation would impermissibly change the principle of operation of a 2-step treatment.

For all of these reasons, *Lange* does not anticipate claims 39 and 62-64. Appellants therefore request that this improper rejection be reversed.

D. Rejection Under 35 U.S.C.§ 103(a): Claims 38-42, 48, 53-58, and 61-66 Are Patentable Under 35 U.S.C. § 103(a) Over *Lange*, *FDA*, and *Dascalu* in view of *Green People*, *Avre*, *Dreumex*, *Odds*, and *Brinkster*

Claims 38-42, 48, 53-58, and 61-66 stand rejected under 35 U.S.C. § 103(a) as obvious over *Lange*, *FDA*, and *Dascalu* in view of *Green People*, *Avre*, *Dreumex*, *Odds*,

and *Brinkster*. Appellants respectfully submit that the Examiner has not established a *prima facie* case of obviousness; therefore, this rejection is legally improper and should be reversed.

1. The Legal Standard for Obviousness

Several basic factual inquiries must be made in order to determine the obviousness or non-obviousness of claims of a patent application under 35 U.S.C. § 103. These factual inquiries, set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), require the Examiner to:

(1) determine the scope and content of the prior art;

(2) ascertain the differences between the prior art and the claims in issue;

(3) resolve the level of ordinary skill in the pertinent art; and

(4) evaluate evidence of secondary considerations.

The obviousness or non-obviousness of the claimed invention is then evaluated in view of the results of these inquiries. *Graham*, 383 U.S. at 17-18, 148 USPQ 467; *see also KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1734 (2007). As the M.P.E.P. provides, "when considering the obviousness of a combination of known elements, the operative question is thus 'whether the improvement is more than the predictable use of prior art elements according to their established functions.'" M.P.E.P. § 2141. In other words, "in short, the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge." *Id.*

2. The Examiner Has Not Established A *Prima Facie* Case of Obviousness

a) The Examiner's Position

Lange, *Green People*, and *Avre* have already been discussed above with respect to the rejections under 35 U.S.C. §112 (*Lange)* and §102 (all three). Regarding claim 38, the Examiner alleges that *Lange* "does not teach the use of a pH range between about 4.5 to about 6.5" and "only teaches a 'neutral' pH." Final Office Action at 20; *see also* Advisory Action at 20. Citing to *Dreumeux* and *Odds*, the Examiner contends that "a pH range between 6-8 is generally considered to be neutral for shampoo products." *Id.* Thus, the Examiner concludes, "Lange teaches a pH range that overlaps in scope with the present invention (i.e., pH 6-8 overlaps in scope with a pH of about 4.5 to about 6.5." *Id.* According to the Examiner, where the claimed ranges overlap or lie inside ranges disclosed in the prior art or are close enough that one skilled in the art would expect them to have the same properties, a case of obviousness exists. *Id.* at 21; *see also* Advisory Action at 21. The skilled artisan would allegedly "expect pirocton olamine to have the same anti-mycotic properties whether it was at a neutral pH (6-8) or more acid pH (4-5)." *Id.* The skilled artisan would allegedly have been motivated to adjust the pH to 4-5 using lactic acid because of its "favorable bacterio and mycostatic properties." *Id.* at 22; *see also* Advisory Action at 22.

The Examiner also notes that while *Lange* and the *FDA* reference "fail to teach the use of a cyclohexyl radical," *Dascalu* allegedly teaches this. *Id.* at 20-22; *see also* Advisory Action at 21-22. The Examiner concludes that it would have been obvious to use ciclopiroxolamine in the treatment described in *Lange* and *FDA* because *Dascalu*

"explicitly states that ciclopiroxolamine is useful for this purpose." *Id.* at 23; *see also* Advisory Action at 23. In the Examiner's view, a motivation to make this combination lies in *Dascalu*'s alleged teaching that these compounds are a "preferred embodiment." *Id.*; *see also* Advisory Action at 23. The Examiner also suggests that the skilled artisan would have reasonably expected to be successful because *Dascalu* allegedly teaches "several successful examples of using anti-fungal agents like ciclopiroxolamines . . . and it is structurally related to the anti-fungal agents disclosed by the combined references of Lange and FDA." *Id.*; *see also* Advisory Action at 23.

In addition, the Examiner concedes that *Lange* "fails to recite the use of a keratolytic agent." *Id.* at 22; *see also* Advisory Action at 21. The Examiner believes, however, that it would have been obvious to use keratolytic agents "because the FDA explicitly approved this ingredient for its use in treating dandruff and seborrheic dermatitis." *Id.*; *see also* Advisory Action at 22. The skilled artisan would allegedly have been motivated to use salicylic acid with the treatment of *Lange* because "the FDA states that active ingredients like salicylic [sic] acid are 'recognized as safe and effective'" and have had a reasonable expectation of success "because the FDA approved the use [of] keratolytic agents like salicylic [sic] acid for the treatment of dandruff and seborrheic dermatitis and also shows its use with pyrithion zinc, which is . . . disclosed as a preferred embodiment of Lange." *Id.*; *see also* Advisory Action at 22. Appellants traverse this rejection.

b) *The improvement provided by the invention is more than the "predictable use of prior art elements."*

When determining whether an invention is obvious, the Examiner must ask whether the improvement provided by the invention is more than the predictable use of prior art elements according to their established functions. M.P.E.P. §2141, citing *KSR v. Teleflex*,82 USPQ2d at 1396, 127 S.Ct. at 1731 (2007). As Appellants argued in detail above, *Lange* clearly teaches that one phase containing a detergent and a second phase containing an organic acid cannot be mixed together without loss of effectivity. In *Lange*'s words, such a combination is not feasible. In contrast, the claimed invention recites a method of treating SD using the combination of a single composition that has an acidic pH and at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants. Such a combination, according to *Lange*, should not work. Indeed, the skilled artisan would not have "reasonably expected to have been able to" use anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants in an acidic composition in view of what the skilled artisan knew at the time of the invention, e.g., based on reading *Lange*. See M.P.E.P. § 2141. Appellants note that the Examiner has not offered any support to show that the skilled artisan would have "reasonably expected to have been able to" use anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants in an acidic composition. Thus, *Lange*, the principal reference of this rejection, expressly teaches away from the claimed invention, i.e., the combination of a particular composition at acidic pH and a surfactant as claimed. As Appellants noted above, one of ordinary skill in the art would have learned

from *Lange* that a composition containing detergents or surfactants cannot be mixed with an acidic composition to yield a product that is effective for treating SD. Clearly, then, the improvement provided by the presently claimed invention is more than the predictable use of prior art elements according to their established functions.

Adding *FDA*, *Dascalu*, *Green People*, *Avre*, *Dreumex*, *Odds*, and *Brinkster* does not compensate for *Lange*'s teaching away from the invention. One of ordinary skill in the art would not have applied *Dascalu* to the claimed invention, because *Dascalu* teaches compositions containing two active ingredients, a cytotoxic agent and an antifungal agent for treating dandruff, which is a different condition from SD. See Amendment filed on April 24, 2002, at 19 and Reply filed June 4, 2007, at 19. Thus, *Dascalu* does not address compositions in which a 1-hydroxy-2-pyridone is the sole active ingredient against SD nor does this reference teach the combination of an acidic pH, the active ingredient and surfactants all in a single composition even for treatment of dandruff, let alone for the treatment of SD.

As Appellants have noted on the record, the other references cited by the Examiner, *Green People* and *Avre* provide generic background information on certain chemical agents such as sodium laurel sulfate and lauramide DEA. Reply filed June 4, 2007, at 20. These references have no link to a method of treating SD or to the single composition described in claims 38 and 39. *Brinkster* and *Dreumex* appear to provide general background information on the pH scale and the pH of *Dreumex* soap in particular. *Id.* Again, neither of these references has anything to do with a method for treating SD or with the single composition described in claims 38 and 39. *Odds*, like

Lagarde and *Lange*, teaches a combination product, emphasizing the importance of using both components together rather than alone. *Id.*

In contrast to the art cited by the Examiner, the rejected claims recite a method of treating SD using a single composition comprising as a sole active component a 1-hydroxy-2-pyridone.

As the Supreme Court instructed in *KSR*, the factual inquiries provided in *Graham v. John Deere Co.*, continue to apply to the analysis of obviousness. Among these factual inquiries is evidence of secondary considerations, including evidence of commercial success. *See also* M.P.E.P. § 2141. Appellants presented such evidence in a declaration by Mr. Kevin Kriel, attesting to the commercial success of compositions comprising 1-hydroxy-2-pyridone with the claim limitations, using Loprox® Shampoo as an example. The Examiner contends that Appellants have not addressed his "commensurate in scope" and "advertising" arguments in the Final Office Action. *See* Advisory Action at 25 and Final Office Action at 26-27. In the Final Office Action, the Examiner opined that Mr. Kriel stated that "ciclopirox, not all of the currently claimed 1-hydroxy-2-pyridones of formula I, has allegedly produced the increased sales." Final Office Action at 27. Thus, the Examiner concludes, Mr. Kriel's declaration "at best only provides support for ciclopirox." *Id.* The Examiner also suggested that there was "no evidence showing that success was attributable to the merits of Appellant's invention rather than to other factors such as advertising." *Id.* Appellants disagree.

Appellants have explained on the record that advertising alone would not speak to the repeat sales described in Mr. Kriel's declaration. See Supplemental Response filed September 22, 2006, at 8. Advertising may encourage new customers to buy a

product, but if the product is not of good quality and effect, they will not buy more of the product. Loprox® Shampoo is merely an example of these compositions. Thus, Mr. Kriel's declaration provides information on commercial success that is commensurate in scope with the claims on appeal.

In sum, because the Examiner's central reference, *Lange*, expressly teaches away from the claimed invention and the secondary references cited by the Examiner do not remedy this, the invention provides more than "the predictable use of prior art elements" and is not obvious in light of the references cited by the Examiner. Thus, the Examiner has not set forth a *prima facie* case of obviousness. Even if a *prima facie* case of obviousness had been established, Appellants have offered sufficient evidence of commercial success to overcome an obviousness rejection. Because this rejection is not supported by the cited references, the Board should remove this rejection.

E. Claims 38-42, 48, and 61-66 Are Patentable Under 35 U.S.C. § 102(b) or Alternatively Under 35 U.S.C. § 103(a) Over *Verdicchio* in view of *Janniger* and *Dittmar*

According to the Examiner, *Verducchio* discloses "a composition for treating dandruff in a human patient," but "do[es] not explicitly state that these people have seborrheic dermatitis." Final Office Action at 30; *see also* Advisory Action at 26. Relying on *Janniger*, the Examiner suggests that treatment of seborrheic dermatitis "is inherently disclosed because dandruff is a form of Seborrheic Dermatitis." *Id.*; *see also* Advisory Action at 26. *Verdicchio*'s composition allegedly "comprises a sole active component which is hydroxy pyridone such as Octopirox," which "falls within the scope of Applicants' formula I." *Id.* at 30 and 31; *see also* Advisory Action at 26 and 27. The Examiner also suggests that *Verdicchio* discloses "a pH of 'about' and wherein the

composition has pH ranging from about to about 4.5 to 6.5." *Id.* at 31; *see also* Advisory Action at 27. Appellants disagree.

1. *Verdicchio* Does Not Anticipate Claims 38-42, 48, and 61-66

Verdicchio does not teach a method of treating SD. Rather, *Verdicchio* consistently discusses treating dandruff, which is a separate condition from SD, as discussed by Applicant in Section V above and in the declarations discussed in this Appeal Brief. Thus, *Verdicchio* does not inherently teach a method of treating SD and as a result does not teach each and every element of claims 38-42, 48, and 61-66. The Examiner's reliance on *Janniger* is misplaced, because *Janniger* improperly confuses the term "dandruff" with the term "seborrheic dermatitis." The Examiner contends that there is no evidence that *Janniger* confused the definition of SD, but that *Janniger* "merely decided to use a broader definition." Advisory Action at 30. As Appellants explained above with regard to written description, the specification is the most important source for understanding and construing the claimed invention. When considering the term "seborrheic dermatitis," the Board, in the prior appeal in the present case, also turned to the specification rather to extrinsic evidence such as other scientific articles. The use of *Janniger* is yet another example of how the Examiner chooses to override the specification's teaching. SD and dandruff are two different conditions, as the specification teaches, and a reference such as *Verdicchio* that teaches treatment of one (dandruff) does not necessarily teach treatment of the other (SD), unlike the Examiner assumes. In the present case, *Verdicchio* does *not* teach treatment of both conditions and nowhere does it teach SD treatment. Thus, *Verdicchio* does not anticipate claims 38-42, 48, and 61-66.

Moreover, even if one were to consider dandruff as a symptom of SD, which Appellants do not, a reference that may speak to treating a symptom of SD does teach treating SD itself. As Appellants have explained on the record, independent claims 38 and 39 speak to the treatment of a human patient for the disease of SD, and not just a symptom of the disease. *See* Preliminary Amendment filed on February 22, 2005, at 22-24. The preamble of claims 38 and 39 recites: "A method of treating seborrheic dermatitis in a human patient in need thereof." Significantly, the Federal Circuit has held that similar language distinguishes the treatment of a disease from the treatment of mere symptoms of that disease.

In *Jansen v. Rexall Sundown, Inc.*, the Federal Circuit's claim construction as a matter of law illuminates the claim language of claims 38 and 39. See *Jansen v. Rexall Sundown, Inc.,* 342 F.3d 1329, 68 U.S.P.Q.2d (BNA) 1154 (Fed. Cir. 2003). *Jansen's* preamble recited: "*A method of treating* or preventing macrocyclic megaloblastic anemia *in humans* . . . which comprises *administering* a daily oral dosage of a vitamin preparation *to a human in need thereof* . . . ." *Jansen,* 342 F.3d at 1330, 68 U.S.P.Q.2d at 1155 (emphasis added). Similarly, Appellants claims recite, "*A method of treating* seborrheic dermatitis *in a human patient in need thereof* comprising *administering to the patient* an amount effective for the treatment of seborrheic dermatitis of a composition . . . ." Claim 38 (emphasis added). The Federal Circuit held that the claim language at issue in *Jansen* must be interpreted to read on the treatment of a disease, not on treatment of mere symptoms. *Jansen,* 342 F.3d at 1333, 68 U.S.P.Q.2d at 1157-58.

To enforce the idea that treating symptoms does not equate to treating diseases, the *Jansen* panel pointed to a similar case, *Rapoport v. Dement,* 254 F.3d 1053, 59 U.S.P.Q.2d (BNA) 1215 (Fed. Cir. 2001):

> On appeal [in *Rapoport*] we gave weight to the ordinary meaning of the preamble phrase "for treatment of sleep apneas," interpreting it to refer to sleep apnea, *per se*, not just "symptoms associated with sleep apnea." Rapoport argued that the count was unpatentable on the ground that a prior art reference disclosed that a form of the compound recited in the claim could be administered, not for treatment of sleep apnea itself, but for treatment of anxiety and breathing difficulty, a symptom of apnea. We rejected that argument, stating, "There is no disclosure in the [prior art reference that the compound] is administered to patients suffering from sleep apnea *with the intent to cure the underlying condition."* Thus, the claim was interpreted to require that the method be practiced with the intent to achieve the objective stated in the preamble.

Jansen, 342 F.3d at 1333, 68 U.S.P.Q.2d at 1157-58 (*quoting Rapoport,* 254 F.3d at 1059 and 1061, 59 U.S.P.Q.2d at 1219 and 1221, *and adding emphasis*). As in *Jansen* and *Rapoport,* claims 38 and 39 recite "in need thereof," indicating treatment of SD itself. Also, as in *Jansen* and *Rapoport,* the amended claims do not explicitly recite "intent," but the preambles of the claims of *Jansen, Rapoport,* and the present application ought to be interpreted to exclude prior art that fails to reveal any intent to treat the underlying conditions just like the preambles in *Jansen* and *Rapoport*. Accordingly, the amended claims should be construed to require treatment of a human patient for the disease of seborrheic dermatitis, and not just a symptom associated with the disease.

2. The Combination of *Verdicchio*, *Janniger* and *Dittmar* Does Not Render Claims 38-42, 48, and 61-66 Obvious

The Examiner applies *Verdicchio* and *Janniger* as described above and reasons that the rejected claims would have been obvious "because both dandruff and seborrheic dermatitis are produced by the same causative agent, *Pityrosporum ovale*, and is generally treated using the same types of medicinal shampoo (e.g., see Janniger et al. . . .)" Final Office Action at 32 and 33; *see also* Advisory Action at 29. Thus, the Examiner concludes, "it would be prima facie obvious to treat the 'separate' seborrheic dermatitis condition with dandruff shampoo like the dandruff shampoo set forth in Verdicchio." *Id.* at 33; *see also* Advisory Action at 29. The skilled artisan would allegedly have had a reasonable expectation of success because, according to the Examiner, both dandruff and seborrheic dermatitis "are produced from a common microbe, *Pityrosporum ovale* organism." *Id*; *see also* Advisory Action at 29. The Examiner bases a motivation to combine in the alleged teaching in *Dittmar* that "pyridones can be used as 'anti-seborrheic' agents.'" *Id.*; *see also* Advisory Action at 29. Appellants again disagree.

The Examiner also suggests that "oily skin plays a big role in seborrheic dermatitis as exemplified by the word 'seborrhea' which means 'too much oil.'" Advisory Action at 31. Based on this unsupported assertion, the Examiner concludes that "a person of ordinary skill in the art would be motivated to use agents that treat oily skin against seborrheic dermatitis whether such treatments constituted a formalistic treatment of seborrheic dermatitis or not." *Id.*

Appellants note that "seborrhea" (as used in "anti-seborrheic") is not the same as SD. Seborrhea refers to the oil (sebum) of the skin and "anti-seborrheic agents" are used to combat oily skin. SD is a separate disorder, which involves the hyperproliferation of keratinocytes and inflammation. See Leyden declaration at 2; see also Section VII.B.2 above. Therefore, the Examiner incorrectly equates "anti-seborrheic agents" with SD treatments: to the contrary, the terms refer to two separate disorders.

Further, the Examiner's foundation for this obviousness rejection is the perception that dandruff and SD are caused by the same organism. But, as Appellant has explained, at the time of the invention, it was unclear to persons of ordinary skill in the pertinent art as to what causes SD. See Reply filed June 4, 2007, at 23 and 24. A hypothesis that "favored an etiology involving bacteria, yeasts, or both … has remained unsupported." Dermatology in General Medicine, 5th ed., page 2 of 17 (filed as Appendix A of the Wortzman declaration). Some in the art argue that "*P. ovale* is not the causative organism but is merely present in large numbers." *Id.* Other possible causes of seborrheic dermatitis include drugs, neuralgic abnormalities that affect the nervous system, physical factors such as temperature and humidity and nutritional disorders. *Id.* Moreover, *Lange* also instructs that "although yeast cells like Pityrosporum ovale . . . are normally found on the skin, some people do have dandruff while others don't." *Lange* at 1, third paragraph. This teaching argues against *P. ovale* being the causative agent of dandruff because it is not specifically associated with incidents of dandruff.

According to the Examiner, the "best scientific data" indicates that P. ovale is responsible for both dandruff and SD. Advisory Action at 30. However, Appellants have provided evidence from *Lange* and from one of ordinary skill in the art, Dr. Wortzman, who has a Ph.D. in cellular and molecular biology and has been involved in research and development for numerous dermatological products, that there are contrary teachings that do not suggest that *P. ovale* is the cause. Indeed, the Examiner acknowledges that there is "no definitive proof" on the point of whether *P. ovale* causes both dandruff and SD, thus contradicting his own statements in support of the rejection. *Id.*

With regard to *Dittmar*, the Examiner disagrees with Appellants' argument that *Dittmar* teaches away from the claimed invention because *Dittmar* provides a list of additional components that can be used with 1-hydroxy-2-pyridone. Advisory Action at 31. The Examiner contends that there is no teaching away because *Dittmar* does not teach that the invention "will not work" unless multiple ingredients are used. *Id.* A teaching that other additives can be added to the active ingredient coupled with the assumption that the more active ingredients a product has, the more effective it is, a reasonable assumption for the skilled artisan to make, teaches away from a sole active ingredient as recited in the claims.

Because it is unclear what causes the different conditions of dandruff and SD, the Examiner's basis for an expectation of success falls. Indeed, as Appellant has explained, there are significant differences between the symptoms of dandruff and SD. Based on what a person of ordinary skill in the pertinent art would have known at the time of the invention, the skilled artisan would not have reasonably expected to have

been able to use a dandruff treatment as a treatment for SD. The conditions are two different conditions and the cause of each condition was not established in the art at the time of the invention, as demonstrated by, for example, *Lange*'s teaching. Because the Examiner has not shown that claims 38-42, 48, and 61-66 are anticipated or obvious, the Board should reverse this rejection.

F. Provisional Rejection of Claims 38-42, 48, and 61-66 Under the Judicially Created Doctrine of Obviousness-type Double Patenting Over claims 14-23 and 26-29 of U.S. Application No. 10/606,229

The Examiner provisionally rejects claims 38-42, 48, and 61-66 under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 14-23 and 26-29 of copending application number 10/606,229. Final Office Action at 27; see also Advisory Action at 32. According to the Examiner, the claims in both applications are "drawn to the same treatment of seborrheic dermatitis using the same 1-hydroxy-2-pyridone compounds having the same generic formula. *Id.*; see also Advisory Action at 32.

Because this rejection is a provisional rejection and no patentable subject matter has yet been identified in copending application number 10/606,229, Appellants have not yet filed a Terminal Disclaimer in response to this rejection. Appellants note that the '229 application is currently under appeal and thus the final disposition and form of those claims is uncertain. If, however, patentable subject matter is identified in the '229 application, Appellants will file a Terminal Disclaimer in the instant application to obviate this rejection. Nonetheless, at this time, Appellants request removal of this rejection upon allowance of the present claims.

G. Conclusion

For the reasons given above, pending claims 38-42, 48, and 61-66 are allowable, and Appellants respectfully request reversal of the outstanding rejections.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: December 21, 2007

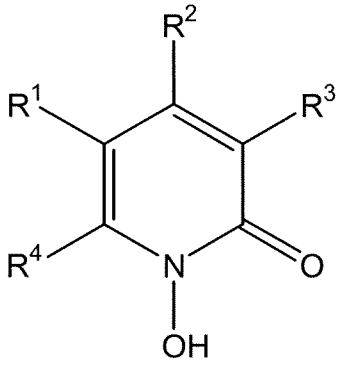
By: Marjana T. Puglielli (Reg No. 52,138)
for Thalia V. Warnement
Reg. No. 39,064

VIII. Claims Appendix

1-37. (Canceled).

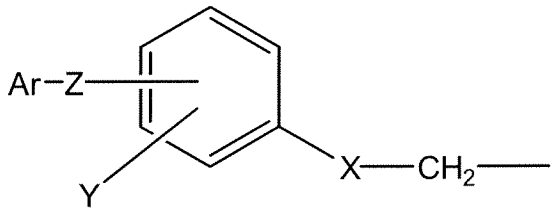
38. A method of treating seborrheic dermatitis in a human patient in need thereof comprising administering to the patient an amount effective for the treatment of seborrheic dermatitis of a single composition, wherein this composition comprises:

(A) a sole active component, which is a 1-hydroxy-2-pyridone of formula I or a pharmaceutically acceptable salt thereof:



(I)

where R^1, R^2, and R^3, which are identical or different, are H or alkyl having 1 to 4 carbon atoms, and R^4 is a saturated hydrocarbon radical having 6 to 9 carbon atoms or a radical of formula II:



(II)

where:

X is S or O;

Y is H, or 1 or 2 identical halogen atoms, or a mixture of 2 different halogen atoms;

Z is a single bond, or

a linking radical comprising

(1) O, or

(2) S, or

(3) $-CR_2-$, where R is H or (C_1-C_4)-alkyl, or

(4) from 2 to 10 carbon atoms linked in the form of a straight or branched chain, which optionally further comprises one or more of the following:

(i) a carbon-carbon double bond, and

(ii) O, S, or a mixture thereof, wherein if 2 or more O or S atoms or a mixture thereof are present, each O or S atom is separated by at least 2 carbon atoms; and,

in any of the foregoing linking radicals, any remaining free valences of the carbon atoms of said linking radical are saturated by H, (C_1-C_4)-alkyl, or a mixture thereof;

and

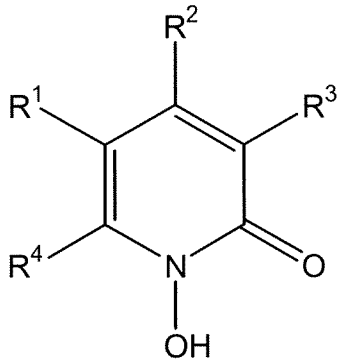
Ar is an aromatic ring system having one or two rings, the aromatic ring system being unsubstituted or substituted by one, two, or three radicals, which are identical or different, and are chosen from halogen, methoxy, (C_1-C_4)-alkyl, trifluoromethyl, and trifluoromethoxy; and

(B) at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants; and

wherein the composition has a pH ranging from about 4.5 to about 6.5.

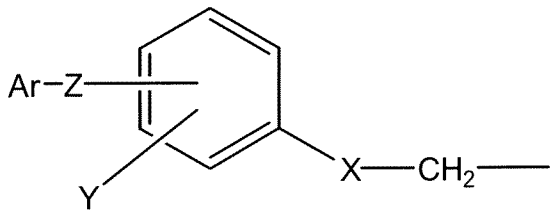
39. A method of treating seborrheic dermatitis in a human patient in need thereof comprising administering to the patient an amount effective for the treatment of seborrheic dermatitis of a single composition, wherein this composition comprises:

(A) a sole active component, which is a 1-hydroxy-2-pyridone of formula I or a pharmaceutically acceptable salt thereof:



(I)

where R^1, R^2, and R^3, which are identical or different, are H or alkyl having 1 to 4 carbon atoms, and R^4 is a saturated hydrocarbon radical having 6 to 9 carbon atoms or a radical of formula II:



(II)

where:

X is S or O;

Y is H, or 1 or 2 identical halogen atoms, or a mixture of 2 different halogen atoms;

Z is a single bond, or

a linking radical comprising

(1) O, or

(2) S, or

(3) $-CR_2-$, where R is H or (C_1-C_4)-alkyl, or

(4) from 2 to 10 carbon atoms linked in the form of a straight or branched chain, which optionally further comprises one or more of the following:

(i) a carbon-carbon double bond, and

(ii) O, S, or a mixture thereof, wherein if 2 or more O or S atoms or a mixture thereof are present, each O or S atom is separated by at least 2 carbon atoms; and,

in any of the foregoing linking radicals, any remaining free valences of the carbon atoms of said linking radical are saturated by H, (C_1-C_4)-alkyl, or a mixture thereof;

and

Ar is an aromatic ring system having two rings, the aromatic ring system being unsubstituted or substituted by one, two, or three radicals, which are identical or different, and are chosen from halogen, methoxy, (C_1-C_4)-alkyl, trifluoromethyl, and trifluoromethoxy, and wherein Ar is a bicyclic system derived from biphenyl, diphenylalkane, or diphenyl ether; and

(B) at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants.

40. A method of treating seborrheic dermatitis in a human patient in need thereof as claimed in claim 38 in which the at least one 1-hydroxy-2-pyridone of formula I has a cyclohexyl radical in the R^4 position.

41. A method of treating seborrheic dermatitis in a human patient in need thereof as claimed in claim 38 in which the at least one 1-hydroxy-2-pyridone of formula I has an octyl radical of the formula $-CH_2-CH(CH_3)-CH_2-C(CH_3)_3$ in the R^4 position.

42. A method of treating seborrheic dermatitis in a human patient in need thereof as claimed in claim 38 in which the sole active component is 1-hydroxy-4-methyl-6-(4-(4-chlorophenoxy)phenoxymethyl)-2(1H)pyridone, 1-hydroxy-4-methyl-6-cyclohexyl-2(1H)pyridone, or 1-hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2(1H)pyridone, or a pharmaceutically acceptable salt of any of the foregoing.

43-47. (Canceled).

48. A method of treating seborrheic dermatitis in a human patient in need thereof as claimed in claim 38 in which the composition further comprises at least one additional surfactant chosen from anionic, cationic, nonionic, and amphoteric surfactants.

49-60. (Canceled).

61. A method of treating seborrheic dermatitis in a human patient in need thereof as claimed in claim 39 in which the at least one 1-hydroxy-2-pyridone of formula I has a cyclohexyl radical in the R^4 position.

62. A method of treating seborrheic dermatitis in a human patient in need thereof as claimed in claim 39 in which the at least one 1-hydroxy-2-pyridone of formula I has an octyl radical of the formula $-CH_2-CH(CH_3)-CH_2-C(CH_3)_3$ in the R^4 position.

63. A method of treating seborrheic dermatitis in a human patient in need thereof as claimed in claim 39 in which the sole active component is 1-hydroxy-4-methyl-6-(4-(4-chlorophenoxy)phenoxymethyl)-2(1H)pyridone, 1-hydroxy-4-methyl-6-cyclohexyl-2(1H)pyridone, or 1-hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2(1H)pyridone, or a pharmaceutically acceptable salt of any of the foregoing.

64. A method of treating seborrheic dermatitis in a human patient in need thereof as claimed in claim 39 in which the composition further comprises at least one additional surfactant chosen from anionic, cationic, nonionic, and amphoteric surfactants.

65. A method of treating seborrheic dermatitis in a human patient in need thereof as claimed in claim 38, in which the sole active component is a pharmaceutically acceptable salt of a 1-hydroxy-2-pyridone of formula I, and in which the composition

further comprises lactic acid to adjust the pH of the composition to the pH ranging from about 4.5 to about 6.5.

66. A method of treating seborrheic dermatitis in a human patient in need thereof as claimed in claim 39, in which the composition further comprises lactic acid to adjust the pH of the composition.

67. (Canceled).

IX. Evidence Appendix

No evidence is being relied upon herein by the Appellant.

X. Related Proceedings Appendix

Appellants appealed to the Board once before during prosecution of the application on appeal and this appeal was assigned Appeal No. 2004-0309. The Board rendered its decision on Appeal No. 2004-0309 on September 15, 2004. Appellants also filed an Appeal Brief on October 15, 2007, in U.S. Application No. 10/606,229. The ongoing appeal in U.S. Application No. 10/606,229 has not yet been assigned an appeal number.

CPE-JZS
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Paper No. 46

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MANFRED BOHN, KARL THEODOR KRAEMER, and ASTRID MARKUS

Appeal No. 2004-0309
Application No. 09/077,194

HEARD: June 22, 2004

Before WINTERS, MILLS, and GREEN, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the examiner's final rejection of Claims 38-42, 48, and 53 -66, which are all the claims pending in U.S. Application No. 09/077,194.

Introduction

Claims 38, 39, 41, 42, 48, 53, 54, and 56-66 stand rejected under 35 U.S.C. § 103(a) as unpatentable in view of the combined teachings of Durrant et al. (Durrant),

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U.S. Patent No. 4,699,924, issued on October 13, 1987; and Lange, U.S. Patent No. 5,132,107, issued on July 21, 1992. Claims 40 and 55 stand rejected under 35 U.S.C. § 103(a) as unpatentable in view of the combined teachings of Durrant; Lange; and Saint-Leger, U.S. Patent No. 5,650,145, issued July 22, 1997, based on Application No. 08/435,806, filed May 5, 1995.

We have considered applicants' specification and claims, the applied prior art, and the positions of the examiner and applicants on appeal. On consideration of the record as a whole, we find that neither Durrant nor Lange constitutes the closest prior art. Saint-Leger, which was only applied against two dependent claims by the examiner, is the closest prior art. Accordingly, we vacate the examiner's rejections under 35 U.S.C. § 103(a).[1] We also enter the evidence submitted with applicants' Reply Brief received June 9, 2003, including the Declaration of Mitchell S. Wortzman, Ph.D, and exhibits A, B, and C attached thereto: A) Gerd Plewig & Thomas Jansen, Dermatology in General Medicine, 5th ed., CD-ROM (1999); B) Kenneth A. Arndt, Manual of Dematologic Therapeutics, 5th ed. (1995); and C) Handbook of Nonprescription Drugs (American Pharmaceutical Association, Washington DC 1996).[2]

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[1] As stated in Ex parte Zambrano, 58 USPQ2d 1312, 1313 (Bd. Pat. App. & Interf. 2001), "[t]he term 'vacate,' as applied to an action taken by an appellate tribunal, means to set aside or to void. When the Board vacates an examiner's rejection, the rejection is set aside and no longer exists" (footnote omitted).

[2] The exhibits attached to the Declaration of Mitchell S. Wortzman, Ph.D, will be cited herein as Exhibits A, B, or C. All references to page numbers of those exhibits are taken literally from the pagination provided by applicants.

We note applicants' commentary respecting commercial success during the hearing on June 22, 2004, but find no objective evidence of record in support thereof. As discussed more fully infra, we enter new grounds of rejection under the provisions of 37 CFR § 41.50(b).

The Claims

A correct copy of pending claims 38-42, 48, and 53-66 is found in Appendix B attached to applicants' Appeal Brief received December 16, 2002 (Paper No. 33).

Claim 39, the broadest claim on appeal, is directed to a method for treating a human or animal patient in need of treatment for seborrheic dermatitis by administering an effective amount of a composition comprising (1) at least one 1-hydroxy-2-pyridone having formula (I) and (2) at least one surfactant selected from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants.

Claim 38 differs from claim 39 by adding a limitation that the composition has a pH ranging from about 4.5 to about 6.5.

Claim 40 depends from claim 38 and adds the limitation "in which the at least one 1-hydroxy-2-pyridone of formula (I) comprises a cyclohexyl radical in the R^4 position."

Claim 48 depends from claim 38 and adds the limitation "in which the pharmaceutical composition further comprises at least one additional surfactant chosen from anionic, cationic, nonionic, and amphoteric surfactants."

Claim 59 is directed to a method for treating a human or animal patient in need of treatment for seborrheic dermatitis by administering an effective amount of a composition comprising (1) at least one 1-hydroxy-2-pyridone having formula (I), (2) at least one surfactant selected from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants, and (3) at least one keratolytic agent.

Claim 61 depends from claim 59 and adds the limitation "in which the at least one 1-hydroxy-2-pyridone of formula (I) comprises a cyclohexyl radical in the R^4 position."

Claim 53 is identical to Claim 59 except for an additional requirement limiting the composition to a pH ranging from about 4.5 to about 6.5.

Claim 55 depends from claim 53 and adds the limitation "in which the at least one 1-hydroxy-2-pyridone of formula I comprises a cyclohexyl radical in the R^4 position."

Claim 66 is directed to a method for treating a human or animal patient in need of treatment for seborrheic dermatitis by administering an effective amount of a composition comprising (1) at least one 1-hydroxy-2-pyridone having formula (I), (2) at least one surfactant selected from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants, and (3) lactic acid.

Claim 65 is essentially identical to Claim 66 except for an additional requirement limiting the composition to a pH ranging from about 4.5 to about 6.5,

Claim Interpretation

The claimed inventions are directed to methods for treating a patient in need of treatment for seborrheic dermatitis. We interpret the phrase "treating a human or animal patient in need of treatment for seborrheic dermatitis" as treating a patient afflicted with any form of seborrheic dermatitis for any one or more of the symptoms associated with that disorder.

We are mindful that applicants' specification defines seborrheic dermatitis as follows (Specification, p. 1, l. 3-7):

> Seborrheic dermatitis is understood as meaning a disorder of the scalp which differs from simple dandruff by the presence of erythema as a sign of inflammation, by the greater degree of scaling with occasional itching and burning, and by the occurrence of eczematous changes to other body sites.

Although seborrheic dermatitis may differ from simple dandruff in symptomatic degree or kind, nonetheless, applicants' claims are directed to methods "for treating a human or animal patient in need of treatment for seborrheic dermatitis" (emphasis added to claim language). Giving the claim language its broadest reasonable interpretation consistent with the specification, we conclude that patients in need of treatment for seborrheic dermatitis reasonably may be treated for dandruff or any one or more of the other symptoms associated with seborrheic dermatitis. See In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989)("During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow"). Therefore, a prior art method that describes treating a patient for at least one symptom associated

with seborrheic dermatitis is construed to anticipate or render obvious a method for treating a patient in need of treatment for seborrheic dermatitis.

Seborrheic dermatitis is characterized by a variety of symptoms. The disorder is often associated with increased sebum production (seborrhea). (Exhibit A, page 1). Other symptoms may include: patchy lesions with margins, mild inflammation, and oily, yellowish scales. (Exhibit C, page 551).

Symptoms of seborrheic dermatitis range in degree from mild to severe. Although symptoms can be severe, "[a]symptomatic, fluffy white dandruff of the scalp represents the mild end of the spectrum of seborrheic dermatitis and has been referred to as pityriasis sicca." (Exhibit A, page 8). Thus, fluffy white flakes of the scalp are associated with both seborrheic dermatitis and simple dandruff. It follows that (1) treating dandruff, viz., fluffy white flakes, also constitutes treating a symptom of seborrheic dermatitis; and (2) an invention for treating dandruff would likely be useful for treating at least one symptom of seborrheic dermatitis. In fact, "[m]any cases of seborrheic dermatitis will respond to the same nonprescription drug regimen used to treat dandruff." (Exhibit C, page 550, column 2, lines 2-4).

Applicants submitted the declaration of Mitchell S. Wortzman with their Reply Brief. Wortzman concludes that "[o]ne of ordinary skill in the art would not find it obvious to use a certain composition to treat seborrheic dermatitis, merely because the same composition is used to treat dandruff." (Declaration of Mitchell S. Wortzman,

page 2, seventh paragraph). Again, we emphasize that the claimed invention is not directed to a method for successfully treating every symptom associated with, or eradicating, seborrheic dermatitis. Nor is it directed to a method of treating a human or animal patient having the classic, well-known disorder of patchy seborrheic dermatitis. (Exhibit A, page 8). The claimed invention is directed to a method for treating a patient "in need of treatment for seborrheic dermatitis." It cannot be gainsaid that "[m]any cases of seborrheic dermatitis will respond to the same nonprescription drug regime used to treat dandruff." (Exhibit C, page 550, column 2, lines 2-4).

New Grounds of Rejection

I. 35 U.S.C. § 102

Claim 39 is rejected under 35 U.S.C. § 102 as anticipated by Saint-Leger. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir.), cert. denied, 484 U.S. 827 (1987). "The reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it." In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990).

Saint-Leger is directed to a method for treating a human patient with a mixture of antifungal and antibacterial compounds. Saint-Leger states (column 2, lines 17-23):

> According to the invention, by the term 'antifungal agent' is intended any substance capable of inhibiting or preventing the growth of yeasts, in particular those found at the surface of the epidermis which is rich in sebaceous glands and especially at the surface of the scalp such as, for example, Pityrosporum ovale and varieties thereof (Pityrosporum orbiculare and Malassezia furfur).

Controlling the growth of Pityrosporum ovale appears to treat a symptom of seborrheic dermatitis. "Pityrosporum ovale, a lipophilic yeast which is a normal inhabitant of the skin, has been hypothesized to be the etiologic agent in seborrheic dermatitis." (Exhibit B, page 164). "Overgrowth of P. ovale may lead to inflammation." (Exhibit A, page 3). Therefore, controlling the growth of that microorganism appears to treat a symptom of seborrheic dermatitis.

In Example 6, Saint-Leger describes a method for treating a male human patient with a composition applied to the scalp, resulting in a change in the seborrhoea. Saint-Leger discloses that "individuals evaluated the variations in their seborrhoea, which could be increased, stable or reduced" (column 6, lines 23 and 24). Table II shows the results of that variation in seborrhoea. Many of the individuals experienced reduced seborrhoea or stable seborrhoea . (Id.). Therefore, Saint-Leger is directed to a method for treating a human patient with at least one symptom of seborrheic dermatitis. We here note that the active ingredients in the composition of Example 6, OCTOPIROX and IRGASAN, are the same active ingredients in the composition of Example 1 of that reference.

Example 1 of Saint-Leger discloses a method which fully meets the method recited in claim 39 using a specified 1-hydroxy-2-pyridone as active ingredient and an

anionic surfactant. Example 1 describes a method of treating a human patient with a shampoo comprising sodium lauryl ether sulfate containing 2.2 mol of ethylene oxide and 1-hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2-(1H)-pyridone, i.e., OCTOPIROX. (Saint-Leger, column 4, Example 1). Applicants' invention recited in claim 39 is directed to a method of treating a human or animal patient in need of treatment for seborrheic dermatitis by administering an effective amount of a composition comprising at least one 1-hydroxy-2-pyridone having formula (I) and at least one surfactant which may be an anionic surfactant. On this record, applicants do not deny that the 1-hydroxy-2-pyridone described by Saint-Leger in Example 1 is a species within the genus of compounds having formula (I) recited in claim 39. Further, applicants' specification teaches that anionic surfactants are preferred for use in the invention; and that examples of anionic surfactants include, inter alia, fatty alcohol ether sulfates that can be used in the form of water-soluble or water-dispensable salts, e.g., the sodium salt (specification, page 6, lines 4-6 and lines 18-31). Thus, Saint-Leger describes the composition recited in claim 39 comprising sodium lauryl ether sulfate and a specific 1-hydroxy-2-pyridone for use in treating a symptom of seborrheic dermatitis.[3]

II. 35 U.S.C. § 102 or 35 U.S.C. § 103

Claims 38-42 and 48 are rejected under 35 U.S.C. § 102 as anticipated by or, in the alternative, under 35 U.S.C. § 103 as unpatentable over Saint-Leger.

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[3] As stated in In re Ruscetta, 255 F.2d 687, 689-690, 118 USPQ 101, 104 (CCPA 1958), "it is axiomatic that the disclosure of a species in a reference is sufficient to prevent a later applicant from obtaining generic claims."

Example 1 of Saint-Leger anticipates claim 39. However, claim 38 adds a pH limitation to claim 39 which is not explicitly disclosed by Saint-Leger. As stated in In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977):

> Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on `inherency' under 35 U.S.C. § 102, on `prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products.

Example I of Saint-Leger reasonably appears to include the free form of a 1-hydroxy-2-pyridone, viz., OCTOPIROX, and an anionic surfactant. Applicants' specification states that when using the free form of the active ingredient, as Example 1 of Saint-Leger appears to be using, adjustment of pH to the skin-physiological range of approximately 4.5 to 6.5 is not necessary. (Specification, page 8, lines 29-33). Thus, it reasonably appears that Saint-Leger's Example 1 composition necessarily or inherently has a pH within the pH range of the composition recited in claim 38 and would not need to be adjusted to meet that range. Example 1 otherwise is identical to the claimed invention. On these facts, we believe that the evidence is sufficient to shift the burden of persuasion to applicants to show that the composition described in Example 1 of Saint-Leger does not necessarily or inherently have a pH within the range recited in claim 38. (Id.).

In any event, it would have been apparent to any person having ordinary skill in the art that the recited pH would be inherent in, or an obvious modification of, Saint-Leger's composition for use in treating a symptom of seborrheic dermatitis because Saint-Leger's composition is "formulated in a topically physiologically acceptable medium." (Saint-Leger, abstract). The Lange patent teaches using a physiologically acceptable acid in its second treatment phase. (Lange, abstract).[4] Lange states that the second phase "comprises a physiologically acceptable acid component, or mixture of such components." (Id.). Lange explains (column 5, lines 33-38):

> The acidity of the phase II solution is generally adjusted in the area of pH 3-6, preferred 4-5. The acidity of the phase II composition is adjusted in such a way that after application a situation is reached which is as much as possible in agreement with the natural pH of the skin.

Claim 40 limits claim 38 to at least one 1-hydroxy-2-pyridone or formula (I) comprising a cyclohexyl radical in the R^4 position. Saint-Leger teaches that a suitable antifungal agent for formulation according to his invention is CYCLOPIROX, i.e., 6-cyclohexyl-1-hydroxy-4-methyl-2-(1H)-pyridone (column 2, lines 28 and 29). Saint-Leger thus describes the 1-hydroxy-2-pyridone compound recited in claim 40.

Claim 48 depends from claim 38 and adds a limitation that "the pharmaceutical composition further comprises at least one additional surfactant chosen from anionic, cationic, nonionic, and amphoteric surfactants." In our judgment, that additional

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[4] As stated in In re Baxter Travenol Labs., 952 F.2d 388, 390, 21 USPQ2d 1281, 1284 (Fed. Cir. 1991), "extrinsic evidence may be considered when it is used to explain, but not expand, the meaning of a reference."

limitation does not serve to distinguish over Example 1 of Saint-Leger disclosing not only sodium lauryl ether sulfate containing 2.2 mol of ethylene oxide (anionic surfactant) but also coconut monoisopropanolamide (additional surfactant).

III. 35 U.S.C. § 103(a)

Claims 38-42, 48, and 53-66 are rejected under 35 U.S.C. § 103(a) in view of the combined teachings of Saint-Leger and Lange. The proper focus of an obviousness inquiry is whether "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." See Merck & Co., Inc. v. Biocraft Labs., Inc., 874 F.3d 804, 807, 10 USPQ2d 1843, 1846 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). The test for obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1971). Further, "in considering the disclosure of a reference, is it proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." In re Preda, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968).

Saint-Leger describes or reasonably would have suggested all aspects of the claimed invention for the reasons stated hereinabove except for the keratolytic agent of claims 53 and 59 and the lactic acid of claims 65 and 66. Saint-Leger discloses that

various types of adjuvants or additives are characteristically employed to formulate the compositions (column 3, lines 32-36). As stated by Saint-Leger (id., lines 38-43):

> Among these adjuvants or additives, especially representative are preservatives, stabilizing agents, pH regulators, osmotic pressure modifiers, emulsifying agents, sunscreen agents, antioxidants, fragrances, colorants, anionic, cationic, nonionic, amphoteric or zwitterionic surface-active agents or mixtures thereof, polymers, and the like.

Lange's invention "relates to the control of dandruff and similar scale forming conditions of the skin of the head" (column 1, lines 13-15). Lange discloses that "[o]ne may also use piroctone olamine [OCTOPIROX] in phase II because of its anti-seborrhoeic effect" (column 5, lines 65-66). Thus, Lange, like Saint-Leger, is directed to a method for treating a human patient with a symptom of seborrheic dermatitis.

Lange further discloses adding a keratolytic agent to his treatment composition. Lange teaches that organic acids, such as salicylic acid, "are known to give a therapeutic effect in the treatment of skin disease" (id., lines 24-32). Evidence submitted with the Reply Brief shows that salicylic acid was known as a keratolytic agent to persons having ordinary skill in the art at the time the invention was made. As indicated in the attached references, salicylic acid is a keratolytic agent. (Exhibit A, page 10; Exhibit B, page 166; Exhibit C, page 551). It would have been obvious for persons having ordinary skill in the art at the time the invention was made to add a keratolytic agent, like salicylic acid, to Saint-Leger's treatment compositions, to enhance their therapeutic effect.

Lange also discloses that lactic acid "plays an important physiological role in the structural stability and functional elasticity of the epidermis and keratine proteins" (column 8, lines 11-14). In that light, it would have been obvious for a person having ordinary skill in the art at the time the invention was made to add lactic acid to Saint-Leger's composition for its beneficial effects on the epidermis during treatment.

ORDER

For the reasons stated above, it is: ORDERED that

(1) the examiner's final rejections of claims 38-42, 48, and 53-66 are vacated; and

(2) new grounds of rejection are entered under the provisions of 37 CFR § 41.50(b).

This decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options

with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .
>
> (2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

VACATED: 37 CFR § 41.50(b)

Sherman D. Winters)
Administrative Patent Judge)
)
)
Demetra J. Mills) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
)
)
Lora Green) INTERFERENCES
Administrative Patent Judge)

Finnegan, Henderson, Farabow,
Garrett & Dunner
Franklin Square Bldg., Suite 700
1300 I Street, NW
Washington, DC 20005-3315

dem